DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0449]

"Draft Compliance Program Guidance Manual: Inspection of Medical Devices;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance document entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Devices.'' This revised draft compliance program provides guidance to FDA staff for the enforcement of four medical device postmarket regulations: The quality system (QS) regulation, which includes coverage of sterilization process validation and the use of the guidance on quality systems inspections technique (QSIT); medical device reporting (MDR); medical device corrections and removals; and medical device tracking requirements. This revised draft guidance is intended to represent the agency's current thinking on the inspection of medical device manufacturers, and it is neither final nor in effect at this time.

DATES: Written comments concerning this revised draft guidance must be submitted by (*insert date 90 days after date of publication in the* **Federal Register**).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the revised draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request

to 301–443–8818. Submit written comments concerning the revised draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Allen T. Wynn, Center for Devices and Radiological Health (HFZ–306), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4695.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Devices'' (CP 7382.845). A notice of availability of the draft guidance was published in the **Federal Register** of July 30, 1998 (63 FR 40720). The draft guidance provides guidance to the FDA field and center staff on the inspection and enforcement activities related to the QS/good manufacturing practices (GMP's) regulation (21 CFR part 820), the MDR regulation (21 CFR part 803), the medical device corrections and removals regulation (21 CFR part 806), and the medical device tracking requirements (21 CFR part 821).

The revised draft document contains the following three major differences from the previous draft guidance. First, the QSIT should be used to conduct QS/GMP inspections, including inspections for sterilization processes, to evaluate a firm's manufacturing and QS. Second, part V of the draft guidance document has been revised so that an official action is indicated based on evidence of QS or subsystem(s) deviations that constitute major nonconformities. Third, three inspection programs have been added to cover the requirements of the MDR, medical device corrections and removals, and the medical device tracking regulations.

Inspection of MDR, medical device corrections and removals, and medical device tracking requirements should be conducted during initial or comprehensive inspections. If a subsequent

routine or followup inspection of a firm's corrective and preventive action subsystem suggests a potential QS problem, then these three related regulatory requirements should be assessed.

The agency has adopted GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This revised draft guidance document is issued as a level 1 guidance consistent with GGP's.

This guidance document represents the agency's current thinking on inspection of medical device manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

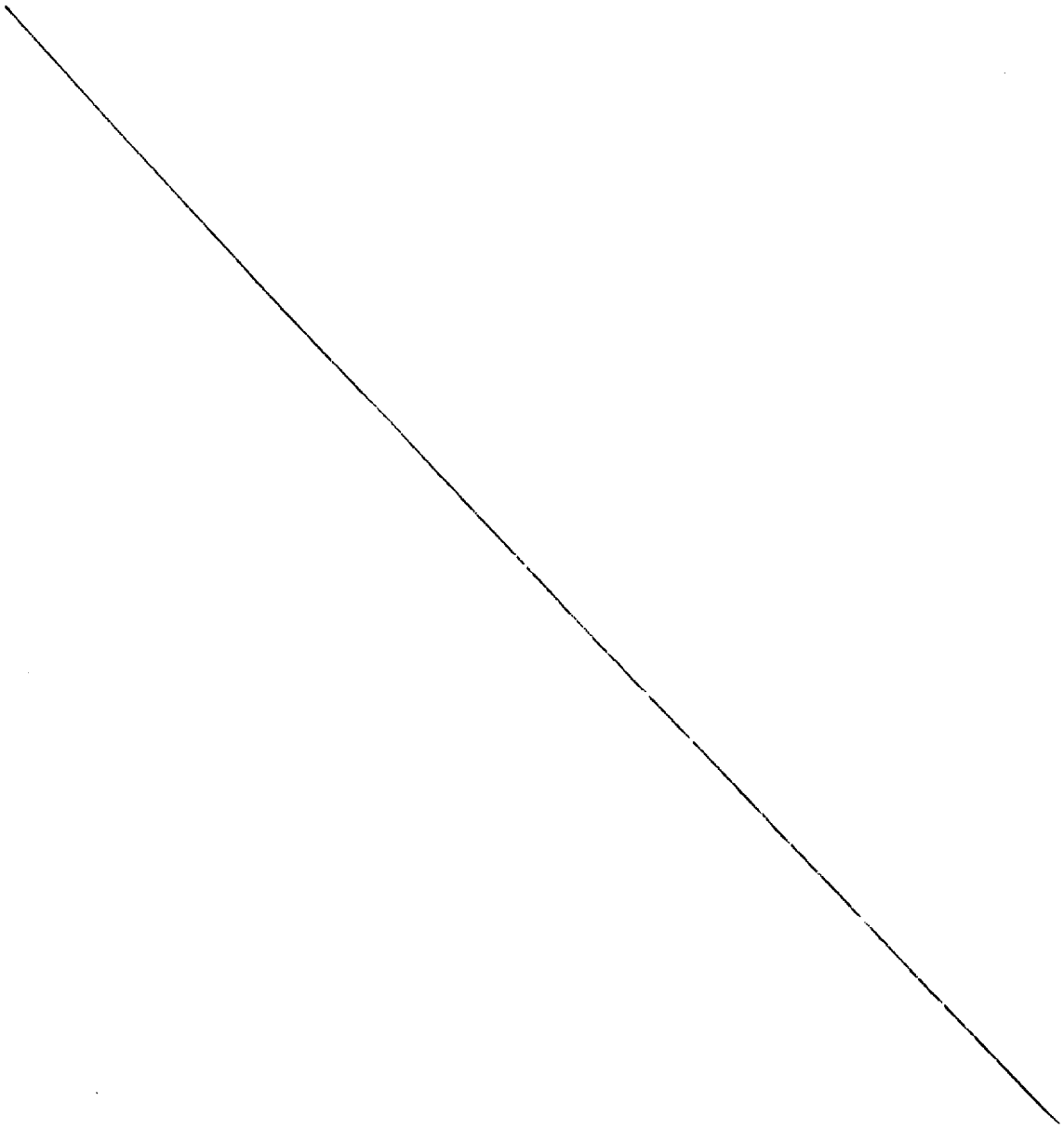
II. Electronic Access

In order to receive the ''Draft Compliance Program Guidance Manual: Inspection of Medical Devices'' (CP7382.845) via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1702), followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the revised draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the ''Draft Compliance Program Guidance Manual: Inspection of Medical Devices'' (CP7382.845), device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at '' http://www.fda.gov/cdrh''.

III. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to Dockets Management Branch (address above) written comments regarding this revised draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found



in brackets in the heading of this document. A copy of the revised draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/28/99
July 28, 1999

Linda S. Kahan,
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